APPENDIX A: 510(K) SUMMARY K061865

JUL 27 2006

Submitter	Guidant Corporation, Cardiac Surgery
Submitter's Address	3200 Lakeside Drive Santa Clara, CA 95054
Telephone	(408) 845-1813
Fax	(408) 845-2077
Contact Person	Christina L. Rowe
Date Prepared	June 29, 2005
Device Trade Name	Guidant FLEX 10® MIS Ablation Probe
Device Common Name	System, ablation, microwave and accessories
Device Classification Name	System, ablation, microwave and accessories
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, features, and intended use of the Guidant FLEX 10® MIS Ablation Probe are substantially equivalent to the predicate device: FLEX 10® Ablation Probe for the Guidant Microwave Ablation System (K013946, February 27, 2002 and K041340, July 28, 2004)
Device description	The FLEX 10® MIS Ablation Probe is designed for use in conjunction with the Guidant 1000 Series Microwave Generator. The Ablation Probe is an intraoperative, sterile, single-use, hand-held device that applies microwave energy to tissue. The Ablation Probe is comprised of a 24-cm-long, rigid handle with position indicators, a metallic shaft, a proximal control tube, a flexible sheath featuring black numbered markings together with right and left hand side markings, a detachable distal control tube, and a guide lead with sutures. The Ablation Probe further includes a 2-m-long insulated coaxial cable, which attaches to the generator output cable connector. The Microwave Generator's output (2450 MHz) is conducted through the output cable connector, into the cabling of the Ablation Probe, and out the antenna at the distal section of the Ablation Probe. The emitted microwave energy is directed toward the target tissue from the active surface opposite the corresponding numbered marking (segment), and creates a continuous lesion approximately 26 mm long. The black side-markings indicate the sides of the sheath. The numbered markings designate each numbered segment of the sheath and correspond to the position indicators on the handle. The ablations are created by independently activating the microwave ablation element at one or more of the corresponding numbered segments, which are selected by moving the sliding ring on the handle.

Indications for Use	The Guidant FLEX 10® MIS Ablation Probe is indicated for the surgical ablation of soft tissue and striated, cardiac, and smooth muscles. The system is a device indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.
Technological characteristics	The Guidant FLEX 10® MIS Ablation Probe incorporates the same fundamental scientific technology as the predicate device.
Performance data	The results of the verification testing demonstrate that the Guidant FLEX 10® MIS Ablation Probe meets the established acceptance criteria and performs in a manner substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Guidant Corporation
c/o Ms. Christina L. Rowe
Principal Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054-2807

Re: K061865
Trade/Device Name: Guidant FLEX 10® MIS Ablation Probe
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II (two)
Product Code: OCL, NEY
Dated: June 30, 2006
Received: July 11 2006

Dear Ms. Rowe:

This letter corrects our substantially equivalent letter of July 27, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k) number (if known)	K061865
Device name	Guidant FLEX 10® MIS Ablation Probe
Indications for Use	The Guidant FLEX 10® MIS Ablation Probe is indicated for the surgical ablation of soft tissue and striated, cardiac, and smooth muscles. The system is a device indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061865